

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

JULIE SPRAFKA,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC., an Indiana Corporation, and MEDICAL DEVICE BUSINESS SERVICES, INC., an Indiana Corporation,

Defendants.

Cause No. 0:22-cv-00331 (DWF/TNL)

**PLAINTIFF'S MEMORANDUM OF
LAW IN OPPOSITION TO
DEFENDANT'S MOTION TO
STRIKE PLAINTIFF'S EXPERT,
TARUN GOSWAMI, D.Sc., FIE**

Plaintiff, Julie Sprafka, by and through her undersigned counsel, respond to Defendant's Motion to Strike Plaintiff's Expert, Tarun Goswami, D.Sc., FIE as follows:

SUMMARY OF ARGUMENT

On June 9, 2023, Defendant filed its expert witness disclosures. Defendant designated Dr. Chantal E. Holy as an expert witness who will provide opinions and testimony about the use of national joint registries in analyzing the performance of Defendant's Attune total knee system. In response, Plaintiff designated Professor Tarun Goswami as a rebuttal expert on June 30, 2023. Professor Goswami's rebuttal opinions are directed toward Dr. Holy's use of the national joint registries. In his report, he specifically identified areas where Dr. Holy's analysis was flawed or inadequate.

The Scheduling Order was silent on the time for designating rebuttal experts. Pursuant to Fed. R. Civ. P. 26(a)(2)(D)(ii), Plaintiff had thirty days from the date Defendant

disclosed Dr. Holy to file Professor Goswami's rebuttal expert report if the evidence is intended solely to contradict or rebut evidence on the same subject matter. A comparison of Dr. Holy's report and Prof. Goswami's rebuttal report establishes that Prof. Goswami's opinion are intended solely to contradict or rebut Dr. Holy's analysis and application of the national registry data she relied on in reaching her opinions.

Plaintiff filed her rebuttal expert report three weeks after receiving Dr. Holy's expert report and therefore her rebuttal report was filed within the thirty-day time-period provided by Fed. R. Civ. P. 26(a)(2)(D)(ii). A party may also make rebuttal disclosures "at least 90 days before the date set for trial or for the case to be ready for trial." Fed. R. Civ. P. 26(a)(2)(D)(i). The deadline for this case to be ready for trial is April 1, 2024. Plaintiff filed Prof. Goswami's report ten months before the date set for the case to be ready for trial. Therefore, Plaintiff has complied with the disclosure requirements of Fed. R. Civ. P. 26(a)(2)(D)(i) and (ii).

Assuming the Court determines Plaintiff's rebuttal disclosure was untimely, the error was substantially justified or substantially harmless. The sanction sought by the Defendants, striking Prof. Goswami's report, is too harsh under the circumstances of this case. Any alleged prejudice can be cured by reopening expert discovery for a limited time in order to allow Defendants to depose Prof. Goswami.

In the alternative, the Court in its discretion may amend the scheduling order for good cause and allow the disclosure of rebuttal experts within thirty days of the other party's disclosure.

BACKGROUND

A. FACTUAL BACKGROUND

Julie Sprafka underwent total knee revision surgery on August 18, 2016. Dr. Andrea Saterbak implanted an Attune total knee system in Plaintiff's right knee. Ms. Sprafka received the first generation Attune knee system with a tibial baseplate. At the time of Ms. Sprafka's surgery, Defendant DePuy had known for over two years that the first generation Attune total knee system required substantial modifications in its design in order to improve the fixation of the tibial baseplate. DePuy had received numerous reports from the field that the tibial baseplate would debond from the cement used to secure the device. DePuy also learned from published peer reviewed journals that the infiltration of lipids into the cement during surgery greatly reduced the fixation of the tibial baseplate. Billi F., PhD, Kavanaugh A., Schalzreid H., Schmalzreid T., MD. Factors influencing the Initial Strength of the Tibial Tray. PMMA Cement Bond. ORS 2014 Annual Meeting. In this same time period, DePuy claims it learned for the first time that aseptic loosening of the tibial baseplate was the single greatest cause for revision surgeries after the first two years following implanting of the total knee system. Sharkey F., et. al., Why are total knee arthroplasties failing today—has anything changed after 10 years. The Journal of Arthroplasty. 2014, 29. 1774-1776.

In 2014, DePuy began developing improvements in the tibial baseplate including recessed pockets in the underside of the tibial baseplate that would allow greater cement penetration and it increased the surface roughness of the tibial baseplate in an attempt to

improve the cement adhering to the tibial baseplate. DePuy labeled this second generation Attune as the Attune S+. The changes in the design of the tibial baseplate to include recessed pockets and the increased surface roughness were the only design changes made to the Attune total knee system. DePuy represented in its sales materials that the improvements to the tibial base “added features designed to provide greater residual pull off strength under a range of simulated intraoperative conditions and the presence of lipid infiltration and motion.”

Despite knowing the first generation Attune tibial baseplate had inferior fixation, DePuy continued to market the Attune without providing surgeons or patients with any warning the design of the tibial baseplate increased the risk of aseptic loosening. DePuy also intentionally failed to disclose the second generation Attune S+ greatly improved the fixation of the tibial baseplate and greatly reduced the risk of aseptic loosening.

After four years of pain, Julie Sprafka sought a second opinion with Dr. Kristopher Breien on June 10, 2020. Julie Sprafka reported that she had excruciating pain when she first stood up and began to walk. Her report was consistent with the pain patients experienced when the tibial baseplate was loose in their knee.

Dr. Breien was familiar with the Attune tibial baseplate debonding from his personal experience with other patients that required revision surgery. Dr. Breien ordered a bone scan which showed a lucent line around the keel of the tibial baseplate. This finding is persuasive evidence that the tibial baseplate in Ms. Sprafka’s knee had debonded from the cement and was now loose without fixation.

Dr. Breien performed a revision surgery on September 15, 2020. During the surgery he observed fluid coming out from around the tibial baseplate consistent with debonding. When he lightly tapped on the top of the baseplate it came loose without any effort. When he removed the tibial baseplate, he observed there was no evidence of cement adhering to the underside of the tibial baseplate or on the keel. He also saw the cement mantle in the tibia showed no sign of cement adhering to the tibial baseplate. In fact, the baseplate left a perfect hole in the cement mantle. In his deposition, Dr. Breien confirmed Jule Sprafka required the revision surgery solely because the Attune tibial baseplate had debonded. In his opinion, but for the defective design of the tibial baseplate, Ms. Sprafka would not have required the revision surgery.

B. PROCEDURAL BACKGROUND

On August 4, 2021, Julia Rust filed her Complaint against Defendants DePuy Orthopedics, Inc. and Medical Device Business Systems, Inc. (“MDBS”), in the United States District Court for the District of Minnesota, Case No. 0:21-cv-01784-DWF-KMM. On December 3, 2021, the Court entered a Scheduling Order. [DKT 21]. The Scheduling Order did not contain a time for the designation of rebuttal expert opinions.

Plaintiff Paul Quast filed a complaint against DePuy and MDBS, Cause No. 0:22-cv-00331-DWF-DTS, alleging the tibial baseplate had debonded in his knee. On September 7, 2022, Plaintiff Juie Sprafka, Cause No. 0:21-cv-0178-DSD-ECW and Plaintiff Paul Quast, Cause No. 0:22-cv-00331-DWF-DTS filed a Motion to Consolidate the two cases. On December 5, 2022, the Court consolidated the two cases into Case No.

0:22-cv-00331-DWF-DTS. [DKT 40]. The Court directed that the Scheduling Order from the Quast case would be the controlling order. Plaintiff Julie Sprafka had not participated in the drafting of the Quast Scheduling Order, nor did she participate in any exchange with the Magistrate on the provisions of the Scheduling Order. The Quast Scheduling Order was silent on the time for disclosing rebuttal expert opinions.

Pursuant to the Consolidated Scheduling Order, Plaintiff filed her Rule 26(a)(2) expert disclosures on March 13, 2023. [Dkt. 70]. Plaintiff identified Mari Truman as her retained expert and provided her expert report. Plaintiff designated Dr. Andrea Saterbak and Dr. Kristopher Breien as non-retained experts.

At the request of the Defendants, the parties filed a stipulated Motion to Amend the Scheduling Order that would allow Defendants until June 9, 2023, to disclose their experts. [Dkt. 72]. On June 9, 2023, Defendants disclosed two experts: Dr. Michael Reis and Dr. Chantal Holy.

Dr. Reis gave the opinion that “[t]he Attune knee is safe and effective, as demonstrated by the registry data and peer-reviewed literature.” As discussed more fully below, Dr. Holy’s expert opinions were based on her analysis of national registry data.

On June 30, 2023, Plaintiff filed her Rebuttal Expert Disclosure and Prof. Tarun Goswami’s Rebuttal Expert Report. *Ex. 1* The rebuttal expert disclosure and report were filed three weeks after Defendants filed their expert reports. The rebuttal expert disclosure and report were also filed ten months before the April 1, 2024, deadline for the case to be ready for trial. Prof. Goswami’s report was filed solely to contradict or rebut evidence on

the same subject matter provided by Dr. Holy and Dr. Reis based on the use of national registry data. It is important to note Prof. Goswami's Rebuttal Report was disclosed six weeks before the deadline for expert discovery which was August 11, 2023.

ARGUMENT

Defendants seek sanctions under Fed. R. Civ. P. 37(1)(c) for the disclosure of Prof. Goswami's expert report. They also claim his report does not contain rebuttal opinions and they are critical of his use of Artificial Intelligence searches. For the reason discussed below, Plaintiff request the Court deny Defendants' Motion to Strike Prof. Goswami.

A. Plaintiff Disclosed Prof. Goswami's Rebuttal Expert opinions in compliance with Fed. R. Civ. P. 26(a)(2)(D)(i) and (ii).

Rule 26(a)(2)(D)(ii) provides that “[a]bsent a stipulation or court order” a party must disclose rebuttal expert witness reports “within 30 days after the other party’s disclosure,” if the evidence offered in the report “is intended solely to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B) or (C).” For the disclosure of a rebuttal report to be timely under this provision, three things must be true: (1) no stipulation or court order must provide otherwise; (2) the report must be served within 30 days of the report to which it is responding; and (3) the report must be a bona fide rebuttal, that is it must be “intended solely to contradict or rebut evidence on the same subject matter identified by” an opposing expert. Fed. R. Civ. P. 26(a)(2)(D)(ii).

A party may also make rebuttal disclosures “at least 90 days before the date set for trial or for the case to be ready for trial.” Fed. R. Civ. P. 26(a)(2)(D)(i). The deadline for

this case to be ready for trial is April 1, 2024. Plaintiff filed Prof. Goswami's report ten months before the date set for the case to be ready for trial.

Where the Court has not ordered any deadlines for the disclosure of rebuttal witnesses, the general provision of rule 26(a)(2)(D)(ii) applies. *Teledyne Instruments, Inc. v. Cairns*, 2013 U.S. Dist. LEXIS 153497. This is the prevailing rule throughout the country. See *Know How, LLC v. Federated Mut. Ins. Co.*, 2022 U.S. Dist. LEXIS 195255; *Buhr Bros. Inc. v. Michaelis*, No. CIV 12-3014-RAL, 2013 U.S. Dist. LEXIS 52299 (“Most federal courts addressing the issue have concluded that, when a scheduling order is silent on the issue of designation of a rebuttal expert, the rebuttal expert is allowed based on Rule 26(a)(2)(D)(ii) of the Federal Rules of Civil Procedure.”); *Mayou v. Ferguson*, 2008 DSD 8, 544 F. Supp. 2d 899, 900-01 (D.S.D. 2008); *SEC v. Badian*, 2009 U.S. Dist. LECIS 120951; *Dixon v. Certainteed Corp.*, 168 F.R.D. 51, 53-54 (D. Kan. 1996)(holding that neither explicit language of Rule 26(a)(2)(D)(ii) nor its purpose requires that the rebuttal experts be provided within 30 days of original disclosure when trial is more than 90 days away).

Where Plaintiff filed a supplemental or rebuttal expert report within thirty days of the disclosure of the expert to be rebutted, the production of the rebuttal report was timely and the Motion to strike the report was without merit. *Lloyd's Acceptance Corp. v. Affiliated FM Ins. Co.*, 2013 U.S. Dist. LEXIS 127300. See also *Newfield Prod. Co. v. Eighty-Eight Oil LLC*, 2018 U.S. Dist. LEXIS 219502. “The Court’s Rule 16 Scheduling Order is not meant to displace the Federal Rules of Civil Procedure, unless the content of

the scheduling order directly contradicts the scheduling order. When the scheduling order is silent on the issue of designation of a rebuttal expert, the rebuttal expert is allowed based on Rule 26(a)(2)(D)(ii).” Id.

Defendants contend the Scheduling Order should be read to abrogate Plaintiff’s right to secure expert rebuttal evidence. The Scheduling Order is silent on a deadline for the Plaintiff’s disclosure of rebuttal expert witness reports. The silence does not mean that the Plaintiff is prohibited from submitting a rebuttal expert report. Defendants’ interpretation of the rule would effectively preclude the Plaintiff from ever providing an expert rebuttal report if it did not include anticipated rebuttal testimony at the time she filed her initial Rule 26(a)(2) expert reports. Defendants’ interpretation would require Plaintiff to anticipate Defendants would be making a statistical argument based on the use of Registry data at the time she produced her expert reports and disclose expert opinions on Defendants’ defense before Defendants disclosed their expert reports. Defendants would not face this dilemma since they had the benefit of Plaintiff’s expert reports for over three months before it disclosed their expert reports. The effect of the Defendants’ interpretation would be to deny the Plaintiff her due process right to present rebuttal expert evidence in response to the opinions of Defendants’ experts.

The case law relied upon by Defendants is inapplicable to the facts of this case. See *SEC v. Badian*, 2009 U.S. Dist. LEXIS 120951 distinguishing *Eckelkamp v. Beste*, 315 F.3d 863, 872 (8th Cir. 2002) and *Masler v. Fields*, 2007 U.S. Dist. LEXIS 98596. In Eckelkamp, the Plaintiff did not provide a rebuttal expert report within thirty days of

receiving the defendants' expert report and did not move for leave to file the report late until sixteen days after Defendant produced the report. The provisions of 26(a)(2)(D)(ii) did not apply. The SEC court refused to follow Eckelkamp. Similarly, the court in SEC v. Badian distinguished the ruling in Masler. In Masler, the scheduling order set a deadline for the Plaintiff to serve a rebuttal report on the defendant. It provided a deadline for the production of rebuttal witnesses, but it did not provide a deadline for serving a rebuttal report on a third-party defendant. The Court in SEC v. Badian reasoned the Masler court should have allowed Plaintiff to file a rebuttal report to the third-party defendant's expert report. However, Plaintiff also properly failed to address the problem in the "proper way," which was to move to modify the scheduling order once it received the third-party expert report.

Where Plaintiff filed a supplemental or rebuttal expert report within thirty days of the disclosure of the expert to be rebutted, the production of the rebuttal report was timely and the Motion to strike the report was without merit. *Lloyd's Acceptance Corp. v. Affiliated FM Ins. Co.*, 2013 U.S. Dist. LEXIS 127300. See also *Newfield Prod. Co. v. Eighty-Eight Oil LLC*, 2018 U.S. Dist. LEXIS 219502. The Court's Rule 16 Scheduling Order is not meant to displace the Federal Rules of Civil Procedure, unless the content of the scheduling order directly contradicts the scheduling order. When the scheduling order is silent on the issue of designation of a rebuttal expert, the rebuttal expert is allowed based on Rule 26(a)(2)(D)(ii). Id.

The Scheduling Order controlling this case was agreed to in civil no. 22-cv-00331 and entered by the Court before the cases were consolidated. After the cases were consolidated, the Court entered an Order making the Quast Scheduling Order the controlling order. Plaintiff was not included in the discussion of the deadlines in the Quast case, although she agreed to be bound by the Scheduling Order. Since she did not participate in setting the deadlines, the incredibly harsh sanction proposed by the Defendant when the Scheduling Order is silent on the deadline for submitting rebuttal expert reports is even more unjust.

On June 9, 2023, Defendants disclosed expert reports from Dr. Chantal Holy and Dr. Michael Reis based on the analysis of national registry data. On June 30, 2023, Plaintiff disclosed the Expert Rebuttal Report from Prof. Tarun Goswami to rebut, contradict or explain the opinions in Dr. Holy's report and the opinion reached by Dr. Reis. It is undisputed, Plaintiff disclosed her Rebuttal Expert Opinions three weeks after it received Dr. Holy's and Dr. Reis's expert reports.

Under the clear direction of Rule 26(a)(2)(D)(ii), Plaintiff disclosed her rebuttal expert report within thirty days of receiving Defendants' expert reports. In addition, Plaintiff's rebuttal expert disclosure complied with Rule 26(a)(2)(D)(i). Under this provision, a party can submit rebuttal expert disclosures 90 days before trial. Here, the trial has not been set and the deadline for having the case ready for trial is April 1, 2024. Plaintiff complied with the provisions of Rule 26(a)(2)(D)(i) when it disclosed Prof. Goswami's report ten months before the case is set to be ready for trial. Therefore, Plaintiff

filed Prof. Goswami's rebuttal expert report timely, and the Court should not strike the report as untimely.

B. Prof. Goswami's Rebuttal Opinions are “intended solely to contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B) or (C).”

Under Rule 26(a)(2)(D)(ii), rebuttal experts are those who present “evidence that is intended to solely contradict or rebut evidence on the same subject matter identified by another party under Rule 26(a)(2)(B) or (C).” Rebuttal expert opinions must “explain, repel, counteract or disprove” evidence raised by an adverse party. *Know How LLC v. Federated Mut. Ins. Co.*, 2022 U.S. Dist. LEXIS 195255; *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 759 (8th Cir. 2005).

Prof. Goswami's rebuttal expert's opinions solely contradicts, explains, and rebuts the opinions of Defendants' expert Dr. Chantal Holy. Both Dr. Holy and to a lesser extent Dr. Michael Reis used national registry data to support their opinions. In response, Plaintiff disclosed Prof. Tarun Goswami whose rebuttal report directly contradicts, rebuts or explains the deficiencies in Dr. Chantal Holy's expert opinions based on national registry data. Prof. Goswami's expert report also addresses the single vague opinion of Dr. Michael Reis. If Defendants do not call Dr. Holy as a witness or if Dr. Reis does not give any opinions based on the registry data, then Plaintiff would have no reason to call Prof. Goswami. His testimony at trial is limited to a rebuttal of Dr. Holy and Dr. Reis.

Contrary to Defendants' argument, Prof. Goswami's Rebuttal Expert Report is not intended to bolster the opinions of Mari Truman. Rather, it is directly in response to the

opinions and analysis in Dr. Holy's report and secondarily to the unsupported opinion in Dr. Reis's report. Ms. Truman's expert report was issued on March 13, 2023, two and half months before Defendants issued their expert reports and it does not address the opinions or methodology utilized by Defendants' experts. Prof. Goswami's report is tailored to respond to Dr. Holy's opinions without reference to any opinions reached by Mari Truman.

Defendants introduced the analysis of registry data in an attempt to explain how aseptic loosening of the Attune tibial baseplate is a known and expected failure mode. Defendants' use of registry data is a crucial component of their defense. Dr. Holy's and Dr. Reis's opinions based on the use of registry data are therefore an appropriate subject for rebuttal testimony and Prof. Goswami's expert rebuttal testimony would directly contradict the Defendants' experts' analysis and application of national registry data.

Dr. Chantal Holy

Dr. Holy is a highly compensated Johnson & Johnson executive. Johnson & Johnson is the parent corporation of Defendants DePuy and Medical Device Business Systems.

In her June 9 expert report, she claims she performed a "meta-analysis" based on published data from seven national registries. (Dr. Holy had previously prepared an internal report in 2020 using registry data. She used this report as the foundation for her expert opinions.) *Ex. 3.*

A small group of countries have national registries that track the performance of medical devices. The United States does not have a national registry. The registry data

tracks revisions, but it does not address patients who haven't had revisions surgery even though the Attune tibial baseplate is debonded.

Dr Holy analyzed data from following registries: the United Kingdom (NJR—27,387 patients), Netherlands (LROI—999 patients), Germany (EPRD—5,902 patients), Switzerland (the Geneva Registry—632 patients), Australia (AOANJRR—15,564 patients), and New Zealand (NZJR—7,789 patients). She also used data provided by Kaiser Permanente. In order to protect patient privacy, Kaiser forbids the use of their data in any publication. Kaiser's data is limited to internal use by DePuy. As a result, Dr. Holy's report is not published, and it was not subject to peer review.

Dr. Holy admitted she did not consider the demographic information from the patients including the sex of the patients, the age and activity levels, and the body mass index when she was analyzing the revision rates. She also admitted she did not consider in her analysis the co-morbidity factors that could have influenced the revision rates for the Attune device.

Nevertheless, Defendant is offering Dr. Holy to testify about the result of her alleged “meta-analysis”. She intends to offer the following opinions:

1. “The volume and consistency of the available data are strong evidence that Attune is not revised at a higher rate than other knee devices.”
2. “If the Attune had a characteristic that caused it to be revised at a higher rate than other devices, the large amount of available data would have reflected a difference in revision rates—it did not.”

3. “A small number of patients presented with aseptic loosening. Across all registries, there was no indication that this number of patients was any different from expected with any devices.”

Dr. Michael Reis

In his expert report, Dr. Reis gave the opinion that “[t]he Attune knee is safe and effective, as demonstrated by the registry data and peer-reviewed literature.” *Ex. 4.* He did not elaborate but his opinion is primarily based on registry data.

Prof. Tarun Goswami

In response to Dr. Holy’s report and the opinion of Dr. Reis based on registry data, Prof. Tarun Goswami issued his Rebuttal Expert Report regarding the legitimacy of using registry data to determine if the Attune model implanted in Julie Sprafka was defective. Prof. Goswami Curriculum Vitae is attached as *Ex. 2.* His extensive CV demonstrates based on his education, experience, academic study including his teaching, and his publications he has the expertise to analyze the use of registry data in determining whether a medical device is defective.

Prof. Goswami reviewed Dr. Holy’s report and Dr. Reis’s report. He also reviewed the defense expert’s extensive files including the national registry data, and the articles relied upon by Defendants’ experts in forming their opinions.

In his rebuttal report, Prof. Goswami gave the opinion the use of registry data relied upon by Dr. Holy could not be applied to Ms. Sprafka. In his opinion, data extracted for

Dr. Holy's alleged "meta-analysis" was deficient because it "did not consider demographics, disease characteristics, comorbidities, enrollments, baseline measurements, exposures and interventions, outcomes, follow-ups and design elements." He criticized Dr. Holy because her studies were not "peer reviewed." He concluded the "registry data is incomplete to extend its application to the US population."

In section 1.2 of his report, Prof. Goswami prepared Table 1.2.1 in which he identified the page number from Dr. Holy's report and responded with his analysis of the deficiencies in her analysis. Defendants claim they can't understand Prof. Goswami's opinions or find his opinions in his report despite the table identifying the page of Dr. Holy's report and the response to her opinions. For example, Prof. Goswami gave the page number from Dr. Holy's report and then stated the "risk was not defined, across country or all recipients of same device, age, demography, comorbidities, predispositions, etc." He criticized Dr. Holy's conclusions without "citations or tabulated raw data." He also specifically criticized the use of data without knowing the "denominator" or "total revisions". He criticized Dr. Holy's use of data from the registries without knowing the reporting rate for each registry. He maintains Dr. Holy used incomplete relevant data from the three US reporting entities. Prof. Goswami specifically identified that the risk was not properly defined and that it only covers revisions. Dr. Holy did not consider, and she did not have data on the patients who received the Attune device but experienced pain and other symptoms.

In section 1.3 of his report, Prof. Goswami criticized Dr. Holy's failure to do a systematic review of the available literature. He criticized the lack of specific data on the population, interventions and comparators. Dr. Holy did not analyze the outcomes needed to be specific to a particular patient. He was particularly critical of Dr. Holy's use of the literature she did review. Dr. Holy did not screen the collected articles for usability; she did not extract the relevant demographics, disease characteristics, comorbidities, enrollments, baseline measurements, exposures, interventions, outcomes and design; she did not analyze the data for risk and bias including the impact of misclassification of the reason for the revision; and he criticized her methodology in analyzing the data.

In section 1.4 of his report, Prof. Goswami discussed the deficiencies in using the American Joint Replacement Registry. He noted the reporting rates were below 60% for revision total knee arthroplasties ("TKA"). With 40% of the surgeries missing from the data, the outcomes cannot be generalized to all TKA. He also analyzed the reporting rates from the various registries and specifically identified the absence of reporting rates or the low reporting rates in the registries relied upon by Dr. Holy.

Prof. Goswami analyzed the revision rates from the American Joint Registries and identified deficiencies in Dr. Holy's analysis. For example, she did not use data after 2019 but the data shows the Attune market share between 2012 and 2017 was minimal. He concluded: "registry data is incomplete to extend its application to the US population."

In section 1.5 of his report, Prof. Goswami demonstrated the difference in the data collection between the United Kingdom and the American system. The data collected from

the UK do not represent the health condition of an individual. He concluded “registry data is incomplete to extend its application to the US population”.

In his section 1.7 summary, Prof. Goswami provides six different opinions criticizing the use of registry data and Dr. Holy’s “meta-analysis”. Although Dr Holy is not named, when read in context it is readily apparent that Prof. Goswami’s analysis is specifically directed to the opinions contained in Dr. Holy’s report and the conclusion reached by Dr. Reis based on the use of registry data. Prof. Goswami went on to find there was not a “systematic review”. Dr. Holy’s “meta-analysis” did not include the increased rates of aseptic loosening in recent TKA revisions with the Attune device.

In section 3 of his report, Prof. Goswami raised the privacy and ethical considerations that limit the use of registry data. He was critical of Dr. Holy using health data without complying with privacy and ethical considerations. Dr. Holy did not use General Data Protection Regulation and consent requirements in utilizing the data for analysis and decision-making purposes. Without proper consent, Prof. Goswami concluded Defendants cannot use data in their “meta-analysis”. “In Summary, if compliance needed and has not been obtained, the registry data cannot be used.”

In section 4 of his report, Prof. Goswami discusses his use of artificial intelligence in his research into the issues presented by Dr. Holy’s report. Prof. Goswami’s opinions were not based on his search but instead, as discussed in his report, his opinions critical of Dr. Holy’s alleged meta-analysis were based on his experience, education, and training. Prof. Goswami’s report merely published his AI research.

Even a cursory review of Dr. Holy's report and then a review of Prof. Goswami's report demonstrates Prof. Goswami's report contains rebuttal opinions that directly contradict, explain, or rebut Dr. Holy's and Dr. Reis's opinions.

Defendants mischaracterize Prof. Goswami's use of artificial intelligence to conduct research and his opinions. Prof. Goswami published in his report the searches he made as part of his investigation. There is no correlation between these searches and Prof. Goswami's opinions. A review of his report confirms he first analyzed Dr. Holy's report and identified the areas where he disagrees with her methodology, use of registry data and ultimately her opinions. The specific opinions are listed above. He then conducted internet searches as part of his investigation, and he identified the search terms and the responses he received which he identified and included in his report. There is no legal support for excluding an expert because he conducted internet searches using search terms as part of his investigation. It is probable that many experts use internet searches as a part of their investigation. It is not an impermissible technique for investigating a company, a product or total knee arthroplasty. The court's concerns about lawyers using AI has no bearing on this case. More importantly, the use of AI to conduct an internet search should more appropriately be addressed in cross examination. This alone cannot form the basis for excluding Prof. Goswami's opinions.

C. The Rule 37(c)(1) Sanction of exclusion is too severe under the circumstances of this case and the Court can fashion a remedy to address any prejudice to the Defendant without excluding Prof. Goswami's expert rebuttal opinions.

When a party fails to designate a witness in compliance with Rule 26(a) or (e), the district court has “wide discretion to fashion a remedy or sanction as appropriate for the particular circumstances of the case.” Fed. R. Civ. P. 37(c)(1). *Wegener v. Johnson*, 527 F. 3d 587 (8th Cir. 2008). The district court may exclude the information or testimony as a self-executing sanction unless the party’s failure to comply is substantially justified or harmless. Fed. R. Civ. P. 37(c)(1). While sanctions under Rule 37(c)(1) are mandatory, exclusion of evidence should not apply if the offending party’s failure was ‘substantially justified’ or if the failure was ‘harmless’. See *Janvrin v. Cont'l Res., Inc.*, 2016 U.S. Dist. LEXIS 118093 (failure to disclose expert opinions was harmless where the court had not set a trial date and the court can ensure the defendant will have adequate time to prepare for cross-examination); *Zoss v. Protsch*, 2023 U.S. Dist. LEXIS 36275 (late disclosed expert report was harmless where the trial was not imminent); *Voss v. State Farm Fire and Cas. Co.*, 2009 WL 1321910 (D.S.D. 2009) (late disclosure was harmless where the failure to disclose was inadvertent); *Centimark Corp. v. Christofferson*, 2012 U.S. Dist. 78354 (no prejudice where there were no pending dispositive motions and trial was not scheduled).

Exclusion is an extreme sanction and “the district court’s discretion narrows as the severity of the sanction or remedy it elects increases.” *Wegener v. Johnson*, 527 F. 3d 587 (8th Cir. 2008). Excluding evidence is a “harsh penalty and should be used sparingly.” *ELCA Enters. v. Sisco Equip. Rental & Sales*, 53 F.3d 186, 190 (8th Cir. 1995). The rules should be construed, administered, and employed by the court and the parties to secure the

just, speedy and inexpensive determination of every action and proceeding.” Fed. R. Civ.

P. 1.

Excluding an expert witness testimony is too harsh a penalty under the facts of this case. See *Benson v. Giordano*, 2008 U.S. Dist. LEXIS 45024 (“The purpose of the ‘harmless provision’ is to ‘avoid unduly harsh penalties in a variety of situations.’”) (quoting Fed. R. Civ. P. 37 advisory committee’s note (1993)). The court gives “great weight to the importance of the expert testimony, in light of the court’s most basic function, namely the search for and ascertainment of the truth” *Lead GHR Enters., Inc. v. Am. States Ins. Co.*, 2014 U.S. Dist. LEXIS 38860; see also *Citizens Bank of Batesville, Ark. v. Ford Motor Co.*, 16 F.3d 965, 967 (8th Cir. 1994) (“To not allow[the witnesses’] testimony would have been a perversion of the trial process as a search for the truth and could have resulted in a miscarriage of justice.”). Moreover, the court should not “blind[ly] adhere to the constraints of a scheduling order, without proper regard for the bases and effects of non-compliance.” *Lead GHR Enters. Citing Tomlin v. Holecek*, 158 F.R.D. 132, 135 (D. Minn. 1994). The appropriate remedy for the late disclosure is the extension of the discovery deadlines to allow the deposition of the expert witness. *Id.*

Rule 37(c)(1) enumerates several other sanctions the court could impose “in addition to” or “instead of” preclusion. *Lael v. Six Flags Theme Parks, Inc.*, 2014 U.S. Dist. LEXIS 113469. “The sanctions enumerated in the rule are not exclusive and arbitrary but flexible, selective and plural. The district court may, within reason, use as many and as varied sanctions as are necessary to hold the scales of justice even.” 8A Charles Alan

Wright, et. al. *Federal Practice and Procedure: Civil 2d* § 2284 at 612-13 (West 1994); *Lael v. Six Flags Theme Parks, Inc.*, 2014 U.S. Dist. LEXIS 113469; *Middleton v. Hempstead County*, 2020 U.S. Dist. 151803 (court fashioned a remedy that would cure prejudice to defendant by re-opening discovery for a limited purpose).

In determining whether a failure to disclose an expert is substantially justified or harmless, there are four factors a court should consider. These considerations are (1) the importance of the excluded expert testimony; (2) the party's explanation for failure to disclose; (3) the potential prejudice created by permitting use of the expert testimony at trial or on a pending motion; and (4) the ability to cure any prejudice. *Oury v. Rapid City Reg'l Hosp., Inc.*, 2011 U.S. Dist. LEXIS 31806; *Citizens Bank v. Ford Motor Co.*, 16 F.3d 965, 966 (8th Cir. 1994).

1. Importance of the Excluded Testimony

With respect to the first factor, the rebuttal testimony of Prof. Goswami is likely to be significant to this case. Dr. Chantal Holy and to some extent Dr. Michael Reis intend to present evidence to the jury that the use of national registries demonstrate the Attune is not revised more often than other total knee systems and that the revision rate proves the product is not defective. Prof. Goswami's testimony is important to provide the jury with evidence that the use of national registry data is not applicable to an individual patient; the data is unreliable, and that there are severe deficiencies in the data relied upon by the Defendants' experts that will mislead the jury including the lack of analysis of patient demographics, activity levels or comorbidities.

2. Explanation for Disclosure

Plaintiff's explanation for his disclosure of the rebuttal expert report is that the Scheduling Order was silent on the deadlines for disclosing rebuttal experts. Plaintiff justifiably relied upon the provisions of Rule 26(a)(2)(D)(i) and (ii) to determine the deadline for submitting rebuttal reports. The report was submitted three weeks after Defendants disclosed their experts and ten months before the deadline for the case to be ready for trial. Under these circumstances, the timing of Plaintiff's disclosure is entirely justified.

This is not a case where a party failed to meet the disclosure deadlines in the Scheduling Order. Plaintiff disclosed her experts on March 13 pursuant to the Scheduling Order and then agreed to Defendants' request to extend the deadline for disclosing the defense experts. Three weeks after receiving Defendant's expert reports, Plaintiff filed Prof. Goswami's rebuttal expert report. At all times, Plaintiff was attempting to comply with the Scheduling Order and where it was silent with the provisions of Rule 26(a)(2)(D)(i) and (ii). This is not the situation like *Wegener v. Johnson*, 527 F.3d 687, 690(8th Cir. 2008) or *Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1008 (8th Cir. 1998) where the disclosures were late without a reasonable explanation.

3. Prejudice to the Defendants

The prejudice to Defendants is minimal at best. Defendants have not identified any particular prejudice by the timing of the rebuttal expert disclosure. Defendants received the rebuttal report before the end of the time-period for expert depositions. Plaintiff filed

the Rebuttal Expert report on June 30 and the close of expert discovery was August 11. Defendants intentionally chose not to depose Prof. Goswami and by their decision not to depose Prof. Goswami they are now attempting to claim prejudice.

There is no trial date and there are no dispositive motions pending. The deadline for having the case ready for trial is April 1, 2024. Defendants have ten months before the case is scheduled to be ready for trial. Defendants have ample time to prepare for the cross examination of Prof. Goswami. Also, the admission of the rebuttal report will not disrupt the order and efficiency of trial and the rebuttal testimony is important to Plaintiff's right to a fair trial. See *Wegener v. Johnson*, 527 F.3d 687, 690 (8th Cir. 2008). Motion to strike late endorsed expert opinions denied where the prejudice is minimal. *Futurefuel Chem. Co. v. Lonza, Inc.*, 2012 U.S. Dist. LEXIS 207473

4. The Ability to Cure the Prejudice.

Under the present circumstances, blind adherence to the scheduling order is not justified. The court can fashion a remedy more appropriate to the circumstances. See *Oury v. Rapid City Reg'l Hosp., Inc.*, 2011 U.S. Dist. LEXIS 31806. The appropriate remedy for the late disclosure is the extension of the discovery deadlines to allow the deposition of the expert witness. *Lead GHR Enters. Citing Tomlin v. Holecek*, 158 F.R.D. 132, 135 (D. Minn. 1994). Prof. Goswami is available for his deposition which renders the failure to disclose harmless.

The appropriate remedy for the claimed prejudice is to reopen discovery for a limited amount of time in order for Defendant to depose Prof. Goswami. See *Oak Creek*

Inv. Props. V. Am. Elec. Power Serv. Corp., 2020 U.S. Dist. 157032 (the court has discretion to modify its own scheduling order to reopen discovery for a brief period under Rule 16(b)(4) provided there is good cause.); *Sorrell Holdings LLC v. Infinity Headwear & Apparel, LLC*, 2021 U.S. Dist. LEXIS 221459 (a less severe sanction of reopening discovery is appropriate); *New Prime, Inc. v. Mason Dixon Intermodal, Inc.*, 2018 U.S. Dist. LEXIS 247744. (failure to comply with scheduling order not sufficient grounds to exclude expert testimony where Defendant has time to prepare for and take expert's deposition). A Defendant's prejudice is cured if it has enough time to prepare for the use of the expert report at trial. *Ponca Tribe of Indians of Oklahoma v Cont'l Carbon Co.*, 2008 U.S. Dist. LEXIS 97736 (finding two months was sufficient to prepare for the use of a rebuttal expert witness report at trial); *Lael v. Six Flags Theme Parks Inc.*, 2014 U.S. Dist. 48733 (any surprise or harm resulting from untimely disclosure can be cured by amending the scheduling order, if necessary, to allow Defendant adequate time to take depositions and prepare for trial). See also *Smith v. CSAA Fire & Cas., Ins. Co.*, 2018 U.S. Dist. LEXIS 192148 (where there is no trial date and Defendant has enough time to prepare for the use of the rebuttal report at trial the late endorsement was harmless).

A balancing of the factors favors Plaintiff. Defendants have shown no real surprise or prejudice resulting from the Rebuttal report that cannot be mitigated. Here, the factors weigh against the "harsh sanction of striking (Plaintiff's) expert witness." There is enough time for Defendant to prepare for the rebuttal expert testimony before the trial date. Any prejudice can be cured by reopening discovery and allowing Defendants to take the

deposition of Prof. Goswami. Defendants cannot show why re-opening discovery to allow the deposition of Prof. Goswami would not mitigate any harm or prejudice caused by the delayed disclosure.

Considering all of the circumstances of this case, striking the designation of Prof. Goswami as a rebuttal witness and foreclosing him from testifying at trial is too harsh a remedy for a disclosure made within the time frame contemplated by Rule 26(a)(2)(D)(ii) and made more than ten months before trial.

Accordingly, Plaintiff respectfully requests the Court deny Defendants' Motion to Strike Plaintiff's Rebuttal Expert Tarun Goswami.

Dated: August 31, 2023

Respectfully submitted,

/s/Stephen J. Baity

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CERTIFICATE OF SERVICE

I hereby certify that on the 31st day of August 2023, a true and correct copy of the foregoing ***Memorandum of Law In Opposition to Defendant Medical Device Business Services, Inc.'s Motion to Strike Plaintiff's Expert, Tarun Goswami, D.Sc., FIE,*** upon the following counsel of record via electronic mail:

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